DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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GUANGZHOU WONDFO BIOTECH CO., LTD.
C/O JOE SHIA
LSI INTERNATIONAL INC.
504 EAST DIAMOND AVE., SUITE F
GAITHERSBURG MD 20878

August 25, 2014

Re: K142044
Trade/Device Name: CR³ Keyless Split Sample Cup Phencyclidine-Methylenedioxymethamphetamine
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: II
Product Code: LAF, LCM
Dated: July 24, 2014
Received: July 28, 2014

Dear Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CR3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine

Indications for Use *(Describe)*
CR3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine is a rapid test for the qualitative detection of Phencyclidine and Methylenedioxymethamphetamine in human urine at a cutoff concentration of 25ng/mL and 500ng/mL, respectively.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

1. Date: August 21, 2014

2. Submitter: Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City, Luogang District,
Guangzhou, P.R. China 510663

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: CR^3 Keyless Split Sample Cup Phencyclidine – Methylenedioxymethamphetamine

Classification:

Product Code	CFR #
LCM	Unclassified
LAF	21CFR 862.3610

5. Predicate Devices: k130665
Wondfo Multi-Drug Urine Test Cup
Wondfo Multi-Drug Urine Test Panel

6. Intended Use
CR3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine is a rapid test for the qualitative detection of Phencyclidine and Methylenedioxymethamphetamine in human urine at a cutoff concentration of 25ng/mL and 500ng/mL, respectively.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

7. Device Description

The CR3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine test uses immunochromatographic assays for phencyclidine and methylenedioxymethamphetamine. The test is a lateral flow, one step system for the qualitative detection of phencyclidine and methylenedioxymethamphetamine in human urine.

8. Substantial Equivalence Information

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of Phencyclidine and Methylenedioxymethamphetamine in human urine	Same, but also detects other drugs in human urine
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Phencyclidine: 25ng/ml Methylenedioxymethamphetamine: 500ng/ml	Same for Phencyclidine and Methylenedioxymethamphetamine
Configurations	Cup	Cup, Panel
Conditions for Use	Over-the-Counter & Prescription Use	Same

9. Test Principle

The CR3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine test is a rapid test for the qualitative detection of phencyclidine and methylenedioxymethamphetamine in urine samples and contains lateral flow chromatographic immunoassays for phencyclidine and methylenedioxymethamphetamine. Each assay uses a mouse monoclonal anti-drug antibody-dye conjugate, fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibodies coated on the test membranes. When the absorbent end of the test is immersed into a urine sample, the urine is absorbed into the

device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentrations below the target cut-off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that indicates a negative result. When analyte concentration is above the cut-off, analyte molecules bind to the antibody-dye conjugate, preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. No colored band shows in the test region, indicating a potentially positive result. A band should form in the control region (C) of the device regardless of the presence of drug or metabolite in the sample.

10. Performance Characteristics
    1. Analytical Performance
        a. Precision

        Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off , +75% cut-off and +100% cut-off. For each concentration, tests were performed two runs per day for 25 days. All sample aliquots were masked and randomized. The results obtained are summarized in the following tables:

A. For Phencyclidine **(PCP) testing**

Result / PCP	-100% cut-off	-75% cut-off	-50% cut-off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
W11810501CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W11810502CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W11810503CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

B. For Methylenedioxymethamphetamine **(MDMA) testing**

Result / MDMA	-100% cut-off	-75% cut-off	-50% cut- off	-25% cut-off	cut-off	+25% cut-off	+50% cut-off	+75% cut-off	+100% cut-off
W11810501CU5	50-/0+	50-/0+	50-/0+	50-/0+	42+/8-	50+/0-	50+/0-	50+/0-	50+/0-
W11810502CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
W11810503CU5	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

        b. Linearity

Not applicable.

c. Stability

The CR3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine is stable at 4-30^{o}C for 18 months as determined by conducting accelerated and real-time stability testing.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 125 phencyclidine samples and 125 methylenedioxymethamphetamine samples equally distributed at concentrations of -50%, -25%, at the cut-off, +25%, +50% of their respective cut-offs were labeled by a person who prepared them and would not participate in the sample testing. These samples were tested using three different lots by three different operators. Results were all positive at +25% and +50% cut-off and all negative at -25% and -50% cut-off for both phencyclidine and methylenedioxymethamphetamine. The following cut-off values for the test devices have been verified.

Test	**Calibrator**	**Cut-off (ng/ml)**
Phencyclidine (PCP）	phencyclidine	25
Methylenedioxymethamphetamine (MDMA)	methylenedioxymethamphetamine	500

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and to urine containing target drugs (phencyclidine or methylenedioxymethamphetamine) at 25% below and 25% above the cut-off. These urine samples were tested using three batches of the CR3Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine by three different operators. Compounds that showed no interference at a concentration of 100μg/mL are summarized below:

Phencyclidine

Acetaminophen	(-) Y Ephedrine	Oxycodone
Acetophenetidin	Erythromycin	Oxymetazoline
N-Acetylprocainamide	β-Estradiol	Papaverine
Acetylsalicylic acid	Estrone-3-sulfate	Penicillin-G

Aminopyrine	Ethyl-p-aminobenzoate	Pentazocine hydrochloride
Amitryptyline	Fenoprofen	Pentobarbital
Amobarbital	Furosemide	Perphenazine
Amoxicillin	Gentisic acid	Phenelzine
Ampicillin	Hemoglobin	Phenobarbital
Ascorbic acid	Hydralazine	Phentermine
D,L-Amphetamine	Hydrochlorothiazide	L-Phenylephrine
Apomorphine acid	Hydrocodone	β-Phenylethylamine
Aspartame	Hydrocortisone	Phenylpropanolamine
Atropine	O-Hydroxyhippuric	Prednisolone
Benzilic acid	p-Hydroxymethamphetamine	Prednisone
Benzoic acid	3-Hydroxytyramine	Procaine
Benzoylecgonine	Ibuprofen	Promazine
Benzphetamine	Imipramine	Promethazine
Bilirubin	Iproniazid	D,L-Propanolol
Brompheniramine	(±) - Isoproterenol	D-Propoxyphene
Caffeine	Isoxsuprine	D-Pseudoephedrine
Cannabidiol	Ketamine	Quinidine
Cannabinol	Ketoprofen	Quinine
Chloralhydrate	Labetalol	Ranitidine
Chloramphenicol	Loperamide	Salicylic acid
Chlordiazepoxide	Maprotiline	Secobarbital
Chlorothiazide	Meperidine	Serotonin (5-Hydroxytyramine)
(±) Chlorpheniramine	Meprobamate	Sulfamethazine
Chlorpromazine	Methadone	Sulindac
Chlorquine	Methoxyphenamine	Temazepam
Cholesterol	(+) 3,4-Methylenedioxy-amphetamine	Tetracycline
Clomipramine	(+)3,4-Methylenedioxy-methamphetamine	Tetrahydrocortisone, 3acetate
Clonidine	Morphine-3-β-D glucuronide	Tetrahydrocortisone3 (β-D glucuronide)
Cocaine hydrochloride	Morphine Sulfate	Tetrahydrozoline
Codeine	Nalidixic acid	Thiamine
Cortisone	Naloxone	Thioridazine
(-) Cotinine	Naltrexone	D, L-Tyrosine
Creatinine	Naproxen	Tolbutamide
Deoxycorticosterone	Niacinamide	Triamterene
Dextromethorphan	Nifedipine	Trifluoperazine
Diazepam	Norcodein	Trimethoprim
Diclofenac	Norethindrone	Trimipramine
Diflunisal	D-Norpropoxyphene	Tryptamine
Digoxin	Noscapine	D, L-Tryptophan

Diphenhydramine	D,L-Octopamine	Tyramine
Doxylamine	Oxalic acid	Uric acid
Ecgonine hydrochloride	Oxazepam	Verapamil
Ecgonine methylester	Oxolinic acid	Zomepirac

Methylenedioxymethamphetamine

4-Acetamidophenol	(L) – Epinephrine	Perphenazine
Acetophenetidin	Erythromycin	Phencyclidine
N-Acetylprocainamide	β-Estradiol	Phenelzine
Acetylsalicylic acid	Estrone-3-sulfate	Phenobarbital
Aminopyrine	Ethyl-p-aminobenzoate	Phentermine
Amitryptyline	Fenoprofen	Trans-2-phenylcyclopropyl amine hydrochloride
Amobarbital	Furosemide	L-Phenylephrine
Amoxicillin	Gentisic acid	β-Phenylethylamine
Ampicillin	Hemoglobin	Phenylpropanolamine
L-Ascorbic acid	Hydralazine	Prednisolone
Apomorphine	Hydrochlorothiazide	Prednisone
Aspartame	Hydrocodone	Procaine
Atropine	Hydrocortisone	Promazine
Benzilic acid	O-Hydroxyhippuric acid	Promethazine
Benzoic acid	3-Hydroxytyramine	DL-Propranolol
Benzoylecgonine	Ibuprofen	D-Propoxyphene
Bilirubin	Imipramine	D-Pseudoephedrine
(±) - Brompheniramine	Iproniazid	Quinacrine
Buspiron	(±) – Isoproterenol	Quinidine
Caffeine	Isoxsuprine	Quinine
Cannabidiol	Ketamine	Ranitidine
Cannabinol	Ketoprofen	Salicylic acid
Chloralhydrate	Labetalol	Secobarbital
Chloramphenicol	Levorphanol	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Loperamide	Sulfamethazine
Chlorothiazide	Maprotiline	Sulindac
(±) - Chlorpheniramine	Meperidine	Sustiva
Chlorpromazine	Meprobamate	Temazepam
Chlorquine Methylphenidate	Methadone	Tetracycline
Cholesterol	Morphine-3-β-Dglucuronide	Tetrahydrocortisone, 3-acetate
Clomipramine	Morphine sulfate	Tetrahydrocortisone 3-(β-Dglucuronide)

Clonidine	Nalidixic acid	Tetrahydrozoline
Cocaethylene	Naloxone	Thebaine
Cocaine hydrochloride	Naltrexone	Theophynine
Codeine	Naproxen	Thiamine
Cortisone	Niacinamide	Thioridazine
(-) Cotinine	Nifedipine	Tolbutamide
Creatinine	Nimesulidate	Trans-2-phenylcyclopropylamine
Deoxycorticosterone	Norcodein	Trazodone
Dextromethorphan	Norethindrone	Triamterene
Diclofenac	D-Norpropoxyphene	DL-Tyrosine
Diazepam	Noscapine	Trifluoperazine
Diflunisal	D,L-Octopamine	Trimethoprim
Digoxin	Oxalic acid	Trimipramine
Dicylomine	Oxazepam	Tryptamine
Diphenhydramine	Oxolinic acid	D L-Tryptophan
5,5 - Diphenylhydantoin	Oxycodone	Tyramine
Doxylamine	Oxymetazoline	Uric acid
Ecgonine hydrochloride	Papaverine	Verapamil
Ecgonine methylester	Penicillin-G	Zomepirac
(-) – Ψ-Ephedrine	Pentazocinehydrochloride	
[1R,2S](-) Ephedrine	Pentobarbital	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. The target drug (Phencyclidine or Methylenedioxymethamphetamine), its drug metabolites and the related compounds were studied. These samples were tested using three batches of the CR3Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine by three different operators. The drug metabolites and other components were tested at different concentrations. The obtained lowest detectable concentration was used to calculate the cross-reactivity. Results are shown in the following tables.

PCP **(**Phencyclidine**, Cut-off=25 ng/mL)**	**Result**	**% Cross-Reactivity**
Phencyclidine	Positive at 25 ng/mL	100%
4-Hydroxyphencyclidine	Positive at 12,500 ng/mL	0.2%

MDMA (Methylenedioxymethamphetamine**, Cut-off=500 ng/mL)**	**Result**	**% Cross-Reactivity**
Methylenedioxymethamphetamine	Positive at 500 ng/mL	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	Positive at 3000 ng/mL	16.7%
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at 300 ng/mL	167%
d-methamphetamine	>100,000	Not detected
d-amphetamine	>100,000	Not detected

g. Effect of Urinary Density and pH

Twelve urine samples of normal, high, and low specific density ranges (1.000 to 1.035) were collected and spiked with either phencyclidine or methylenedioxymethamphetamine at 25% below and 25% above the corresponding cut-off level. These samples were tested using three batches of the CR3Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine by three different operators.

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.00 to 9.00 in 1 pH unit increments and spiked with phencyclidine or methylenedioxymethamphetamine at 25% below and 25% above the corresponding cut-off levels. These samples were tested using three batches of the CR3Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine by three different operators.

The device performance was found not affected by varying urine density and pH.

2. Comparison Studies

The method comparison for the CR^3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine was performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were masked and randomized. The obtained test results are compared to GC/MS results. The results are presented in the table below:

Phencyclidine

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	3	17	20
	Negative	10	18	9	3	0
Viewer B	Positive	0	0	3	16	20
	Negative	10	18	9	4	0
Viewer C	Positive	0	0	3	17	20
	Negative	10	18	9	3	0

Discordant table:

Viewer	Sample number	GC/MS result	Viewer result
Viewer A	PCPC1061	24	positive
Viewer A	PCPC1062	24	positive
Viewer A	PCPC1064	23	positive
Viewer A	PCPC1063	26	negative
Viewer A	PCPC1065	25	negative
Viewer A	PCP1214	25	negative
Viewer B	PCPC1061	24	positive
Viewer B	PCPC1062	24	positive
Viewer B	PCPC1064	23	positive
Viewer B	PCPC1063	26	negative
Viewer B	PCPC1065	25	negative
Viewer B	PCP1213	27	negative
Viewer B	PCP1214	25	negative
Viewer C	PCPC1034	21	positive
Viewer C	PCPC1062	24	positive
Viewer C	PCPC1064	23	positive
Viewer C	PCPC1065	25	negative
Viewer C	PCP1213	27	negative
Viewer C	PCP1214	25	negative

Methylenedioxymethamphetamine

Group / Operators		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	4	16	20
	Negative	10	10	16	4	0
Viewer B	Positive	0	0	3	17	20
	Negative	10	10	17	3	0
Viewer C	Positive	0	0	4	17	20
	Negative	10	10	16	3	0

Discordant table:

Viewer	Sample number	GC/MS result	viewer results
Viewer A	MDMA5213	498	positive
Viewer A	MDMA5216	482	positive
Viewer A	MDMA5223	494	positive
Viewer A	MDMA5224	478	positive
Viewer A	MDMAC5061	532	negative
Viewer A	MDMAC5062	544	negative
Viewer A	MDMAC5063	509	negative
Viewer A	MDMAC5064	521	negative
Viewer B	MDMA5216	482	positive
Viewer B	MDMA5223	494	positive
Viewer B	MDMA5224	478	positive
Viewer B	MDMAC5061	532	negative
Viewer B	MDMAC5063	509	negative
Viewer B	MDMAC5064	521	negative
Viewer C	MDMA5213	498	positive
Viewer C	MDMA5213	498	positive
Viewer C	MDMA5223	494	positive
Viewer C	MDMA5216	482	positive
Viewer C	MDMAC5061	532	negative
Viewer C	MDMAC5063	509	negative
Viewer C	MDMAC5064	521	negative

Lay-user study

A lay user study was performed at three intended user sites with 260 lay persons, of which, 20 tested for drug-free samples, 120 for phencyclidine samples, 120 for methylenedioxymethamphetamine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to

>50 years. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cut-off by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers, blind-labeled and randomized. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below:

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
Drug -free	-100%	20	20	0	100%
Phencyclidine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Methylenedioxy-methamphetamine	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	3	17	85%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed A Flesch-Kincaid reading analysis was performed on the package insert and the score revealed a reading grade level of less than 7.

3. Clinical Studies

   Not applicable

11. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that CR^3 Keyless Split Sample Cup Phencyclidine - Methylenedioxymethamphetamine is substantially equivalent to the predicate.